U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

PHARMACEUTICAL SERVICES AND MEDICATION MANAGEMENT

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By Order of the Acting Assistant Director
Stewart D. Smith, DHSc/s/

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1. **PURPOSE:** This issuance establishes the policies and procedures for pharmaceutical services provided by the U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) medical clinics.

2. **APPLICABILITY:** This directive applies to all IHSC personnel, including but not limited to, Public Health Service (PHS) officers, civil service employees and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned or contracted detention facilities and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ. Federal contractors are responsible for the management and discipline of their employees supporting IHSC.

3. **AUTHORITY:** The relevant laws and regulations pertaining to the medical and pharmaceutical care provided to persons detained by ICE provide the authority to establish policy and management practices in this issuance.

   3-1. Pharmacist's Manual - An Informational Outline of the Controlled Substances Act, United States Department of Justice, Drug Enforcement Administration (DEA), Office of Diversion Control;

   3-2. Title 42, U.S. Code, Section 252 (42 U.S.C. § 252), Medical Examination of Aliens;

   3-3. The Comprehensive Drug Abuse Prevention and Control Act of 1970;

   3-4. Title 21, Code of Federal Regulations, Volumes 1, 4, 5, and 9;

   3-5. Section 322 of the Public Health Service Act, as amended, Title 42 U.S. Code, Section 249(a) (42 U.S.C. § 249(a)), Medical Care and Treatment

of Quarantined and Detained Persons;

3-6. Title 16, Code of Federal Regulations, Part 1700 (16 CFR 1700), Poison Prevention Packaging Act of 1970 Regulations;

3-7. The Privacy Act of 1974, Title 5, U.S. Code, Section 552(a) (5 U.S.C. § 552(a)), as applied in the Department of Homeland Security (DHS)/ICE-013 Alien Health Records System of Records Notice, 80 Federal Register 239 (January 5, 2015).

4. POLICY: IHSC provides quality pharmacy services and ensures compliance with appropriate regulatory requirements through a cost effective drug and medication supply management plan. This plan includes compliance activities and processes; protocols for daily operations related to pharmacy services and medication management; effective prescription practices and procedures for the administration of medications and controlled substances. IHSC pharmacies and pharmacists maintain compliance with ICE detention standards, federal regulations and federal statutes.

4-1. Pharmacy Operations. IHSC pharmacies comply with all applicable state and federal regulations regarding prescribing, dispensing, administering, procuring, and disposing of pharmaceuticals. IHSC pharmacies maintain procedures for the timely procurement, dispensing, distribution, accounting, and disposal of pharmaceuticals. Records are maintained as necessary to ensure adequate control of and accountability of all medications and medications are kept under the control of appropriate staff members.

a. Equipment in the pharmacy should at least include:

(1) Adequate computer and peripherals;

(2) Refrigerator dedicated to and appropriately labeled for the storage of medications and biologicals;

(3) Stand-alone refrigerator plus a stand-alone, frost-free freezer for Vaccines For Children (VFC) vaccines at facilities participating in the VFC program;

(4) Sink with hot and cold running water;

(5) Adequate HVAC and lighting;

(6) System to monitor temperature control that meets compendia/U.S. Food and Drug Administration (FDA) standards;

(7) Adequate shelving, storage and counter space; and

(8) Appropriate reference materials (e.g., journals, books, electronic or Internet-based reference materials).

b. Staffing. A licensed pharmacist must provide guidance and direction for pharmaceutical services and is responsible for supervising pharmacy technicians. When pharmaceutical services are not provided on-site, IHSC designated regional/central fill pharmacy or contract pharmaceutical services should be established.

c. Orientation. All incoming pharmacy personnel should receive an orientation to develop an understanding of the purpose, function and responsibilities of the department. This orientation includes the following:

(1) Introduction to existing department staff;

(2) Explanation of job description and duties;

(3) Explanation of expected levels of job performance;

(4) Reading of IHSC directives, guides, and operations memoranda;

(5) Completion of all Virtual University required training elements;

(6) Completion of facility orientation, as applicable;

(7) Completion of orientation to pharmacy areas; and

(8) Review of the IHSC Field Orientation Guide.

d. Pharmacy service coverage during the absence of a pharmacist.

(1) Medical clinics with a staff pharmacy technician.

In the absence of a pharmacist, the on-site pharmacy technician fills prescriptions. A physician must review the filled prescriptions prior to dispensing. The physician must also initial each medication container before distribution from the pharmacy;

An IHSC pharmacist at a different IHSC facility may fill and mail prescriptions to a pharmacy that does not have a pharmacist present; and/or

The respective Regional Pharmacy Consultant, in consultation with the IHSC Chief Pharmacist, may determine other available and appropriate options for a pharmacist absence of greater than one week.

(2) Medical clinics without a staff pharmacy technician.

IHSC staff is encouraged to utilize the approved mail order pharmacy system or a contract pharmacy to fill prescriptions during the absence of a pharmacist;

An IHSC pharmacist at a different IHSC facility may fill and mail prescriptions to a pharmacy that does not have a pharmacist present; and/or

The respective Regional Pharmacy Consultant, in consultation with the IHSC Chief Pharmacist, may determine other available and appropriate options for a pharmacist absence of greater than one week.

e. Safety/security of medications.

(1) Security of pharmacies and drug storage areas. Pharmacies and drug storage areas should be secured at all times and access should be limited to authorized pharmacy staff and physicians. Temporary access to the pharmacy may be granted in an emergency situation by the facility lead pharmacist, IHSC Regional Pharmacy Consultant, IHSC Chief Pharmacist, or facility health services administrator (HSA). Non-pharmacy personnel in the pharmacy or drug storage area must be accompanied by IHSC authorized staff and must be under direct visual supervision by the pharmacist or the HSA designee at all times.

(2) Pharmaceuticals should be stored in a secure area with the following features:

A secure perimeter;

Access limited to authorized staff;

Solid walls from floor to ceiling with a solid ceiling;

A secure entrance door with a high security lock; and

A secure medication storage area.

(3) Medication storage. Medications should be stored based on drug category, security requirements and manufacturer's recommendations. When space permits, medications should be stored in alphabetical order by generic name within each of the following categories: oral-inhalant, oral-internal, external-topical, injectable, ophthalmic, otic, nasal-inhalant, scheduled medications, abusable supplies, flammable items and thermo-labile items. All scheduled medications in the pharmacy should be stored in a double lock cabinet. All medications are stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. Antiseptics, other medications for external use, disinfectants are stored separately from internal and injectable medications. Medications requiring special storage (e.g., refrigeration) for stability are so stored.

(4) Emergency drugs and medical supplies should be stored in an after hour medication cabinet and urgent care cart that is secured, and an inventory system should be maintained for accountability. If a nurse or provider removes any pharmaceutical item from this stock, they must notify pharmacy of this removal. An adequate and proper supply of antidotes and other emergency medications and related information are readily available to staff. The poison control telephone number is posted in areas where overdoses or toxicologic emergencies are likely.

(5) Surplus, damaged and/or expired drugs should be stored in a designated area pending appropriate disposal.

(6) Surplus, damaged and/or expired drugs should be disposed of via the Veterans Administration (VA) Prime Vendor Reverse Distributor whenever possible. If the surplus, damaged or expired drug is a controlled substance, it should be disposed of in compliance with DEA regulations.

(7) Refrigerated medications should be stored in designated refrigerators. Food products should not be stored in refrigerators designated for medication storage. Refrigerators for medication storage must have a sign posted on the exterior designating that food should not be stored in these refrigerators. If a freezer is required for the storage of medication, it should be a stand-alone freezer.

(8) Pharmacy and drug storage areas should be maintained at a temperature within the manufacturer's recommendations for each medication (typically between 59 degrees Fahrenheit (F) and 80 degrees F).

(9) Medications labeled as, "Keep Refrigerated," should be maintained at a temperature within the manufacturer's recommendations for each medication (typically between 34 degrees F and 46 degrees F).

(10) The pharmacist should perform a daily check on room and medication storage refrigerators on all pharmacy workdays to ensure the room and refrigerator temperatures are within acceptable limits. The pharmacist should maintain written documentation of room and refrigerator temperatures. An electronic temperature recorder should be utilized to verify the refrigerator temperature during days the pharmacy is closed.

(11) If temperatures are noted out of the acceptable range, the pharmacist should contact the IHSC Regional Pharmacy Consultant to determine the viability and disposition of the affected medication(s).

(12) All bulk items in the pharmacy or pharmacy storage areas that pose a security risk (e.g., sharp instruments, syringes, needles, and scissors) should be inventoried weekly; non-bulk items should be inventoried daily. A perpetual written inventory system should be maintained for these items.

f. Procurement of medications.

(1) The first source for all prescription medications is the Veterans Administration (VA) Pharmaceutical Prime Vendor Program. Medications that are available under federal contract should be purchased from this source.

(2) Mail order pharmacy contract services. Mail order contract pharmacy services may be used in all IHSC operated clinics as a back-up system. In selected clinics where prescription volume is not sufficient to justify the services of an on-site pharmacist, the pharmacist is unavailable, or the position of the pharmacist is vacant, mail order should be the primary medication procurement mechanism.

(3) Additional sources for medications are:

Public Health Service Supply Center; Perry Point, Maryland;

Defense depots and military installations;

Private vendors with Federal Supply Schedule contracts; and

Other IHSC sites.

(4) Urgently required products. If a product is not available from the sources listed above, it should be obtained from a local pharmacy utilizing IHSC approved procurement procedures.

(5) Detainees have immediate access to medication. The medical provider must start the order for medications prior to the arrival of medications from the off-site mail order pharmacy using the following available options:

After hour medication cabinet. If the order for a prescription medication must start before the arrival of the medication from the off-site mail order pharmacy, the medical provider or registered nurse (RN) should obtain a three-day supply of the medication from the after hour medication cabinet. (*See* Pharmaceutical Services and Medication Management Guide, VA After Hours Medication, for details); and

Local pharmacy (Script Care, Inc.). IHSC augments the pharmacy services with Script Care, Inc., that allows IHSC-operated health care facilities to obtain medication through a local pharmacy. If the order must start before the arrival of the medication from the off-site mail order pharmacy, and it is not available through the after hour medication cabinet, the medical provider should obtain the prescription medication from a local pharmacy via the Script Care Pharmacy Network.

4-2. Local Pharmacy (Script Care, Inc.). If the provider needs to obtain the prescription medication from a local pharmacy via the Script Care Pharmacy Network, the provider should call in or fax the order to a local participating pharmacy. The Pharmacy Benefit Letter Form should be forwarded to a local pharmacy for plan coverage. As soon as the nurse receives the medication, the MAR (Medication Administration Record) should be created.

4-3. Authorized Prescribers. Health care personnel should only order medications allowable within the respective personnel's scope of practice, as defined by IHSC policy. Medications may be prescribed by the following:

a. Physician;

b. Dentist;

c. Physician assistant (PA) or nurse practitioner (NP) under approved PA and NP guidelines, a copy of which is kept in the pharmacy;

d. RN under approved RN guidelines, a copy of which is kept in the pharmacy;

e. Contract providers based on their state licensing authority; and/or

f. Pharmacist.

(1) The pharmacist should operate within the guidance of an IHSC approved collaborative practice agreement.

(2) The pharmacist should provide immunization services in compliance with approved IHSC guides.

Pharmacist immunization services. An IHSC pharmacist may provide immunization services in accordance with U.S. Centers for Disease Control and Prevention (CDC) guidelines to residents/detainees (hereafter referred to as detainees) as long as the pharmacist has completed appropriate immunization administration training and is empowered to administer immunizations by their state licensing board. Immunizations administered to detainees must be in accordance with IHSC policy regarding vaccinations.

4-4. Written Prescriptions. The provider should enter prescriptions in the electronic health record (eHR), or on IHSC approved paper forms, if the eHR is not available. If a prescription is written on paper forms, these forms should be entered into the eHR in accordance with IHSC directives and guides concerning this subject. Prescriptions then should be delivered and/or sent to the appropriate pharmacy (normally the on-site pharmacy where the provider is located). The forms should be routed to the medical records department for scanning into the eHR, and then the forms should be shredded.

a. Prescription medication names are normally selected from a list available within the eHR. If a needed medication is not listed, the provider should contact the local pharmacist; the local pharmacist should then contact the Regional Pharmacy Consultant to add the medication to the Master Medication List.

b. Prescriptions should be filled with "A" rated generic products listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, if available, unless the brand name product

is available from the VA Pharmaceutical Prime Vendor at an equivalent or better price.

c. Prescribers should provide the following information on each prescription to the pharmacist:

(1) Date of prescription order;

(2) Detainee's name and alien registration number;

(3) Medication name;

(4) Dosage form;

(5) Medication strength and quantity;

(6) Directions for use;

(7) Reason or medical condition for which the medication is prescribed;

(8) Refill information;

(9) Provider's stamped name, title and legal signature, or approved electronic entry of name; and

(10) Facility DEA number, if the prescribed medication is a controlled substance.

4-5. DEA controlled substances and record keeping.

a. A prescription order for a scheduled drug should only be issued by a physician, clinical pharmacist (CP), dentist or mid-level provider (MLP) who is:

(1) Authorized to prescribe scheduled medications by the jurisdiction in which the he/she is licensed to practice (does not apply to federal employees); and

Registered under the Controlled Substances Act or exempt from registration, such as military and U.S. Public Health Service physicians.

a. An MLP who is not individually privileged to prescribe controlled substances must have all orders for controlled substances co-signed by a physician. An MLP may be individually privileged by their supervising physician to prescribe certain controlled substances for specified durations without a physician co-signature, only as permitted

by the MLP's licensure and the IHSC formulary. The "Controlled Substance Prescribing Privileges for IHSC Midlevel Providers" (IHSC Form 921) should be completed upon initial employment with IHSC; this form remains active through the duration of the MLP's current license, unless modified by the supervising physician. Controlled substance privileging should be renewed at the time of the MLP's medical or nursing license renewal.

b. In the absence of a pharmacist, only a physician or a contract pharmacy can dispense scheduled drugs.

c. The prescriber should write or print a separate hard copy prescription and place a wet ink signature for each controlled substance prescription; in addition, the prescriber should enter the prescription into the eHR. The prescriber should deliver each wet-ink signed prescription hard copy to the pharmacist immediately after the medication is ordered.

d. Schedule II medications. The prescriber should enter orders for Schedule II drugs into the patient's eHR and deliver a wet-ink signed hard copy of the prescription to the pharmacy immediately after the order is entered into the patient's eHR. (See also Section 4-10, Verbal Orders.)

e. Schedule III through Schedule V medications. The prescriber should enter the order for Schedule III through Schedule V drug(s) into the patient's eHR and deliver a wet-ink signed hard copy of each prescription to the pharmacy immediately after the order is entered into the patient's eHR, if the provider is on-site. For Schedule III through Schedule V prescriptions where the prescriber is not on-site but has access to the eHR, the provider should enter the prescription into the eHR and call in a verbal prescription to the site pharmacy giving the same prescription order verbally. For Schedule III through Schedule V prescriptions by MLPs needing a physician co-signature where there is an MLP on-site and a covering physician who is not on-site, a copy of the MLP's wet-ink signed prescription should be sent via email to the covering physician to sign electronically and forward to the pharmacy. (See also Section 4-10, Verbal Orders.)

f. When the enterprise eHR system is certified as compliant with Title 21, Code of Federal Regulations, Part 1311 (21 CFR 1311), IHSC's DEA-registered pharmacies may electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions as long as the prescriptions maintain conformity with the Controlled Substances Act and 21 CFR 1311.

g. The pharmacist should develop specific record-keeping procedures for controlled substances that comply with DEA, FDA, IHSC and medical facility requirements that include, but are not limited to: requisitions, receipts, individual prescriptions and issuance/transfer of pharmaceuticals to other medical facilities. In the absence of a pharmacist, a physician or their designee should temporarily accept custody and follow aforementioned requirements for proper record keeping (See Section 4-5 l., Transfer of custody of controlled substances between pharmacists and other parties).

h. The pharmacist should file completed controlled substance paper prescriptions using the following method:

Two separate files, one for Schedule II drugs dispensed and another for Schedule III, IV and V drugs dispensed. Prescriptions for schedule III, IV, and V must be made readily retrievable by marking with a red C not less than one inch high.

i. The pharmacist should maintain the following records:

(1) Official order forms (DEA Form-222) for receipt and sale of Schedule II controlled substances.

(2) Receipts and invoices for Schedule II, III, IV, and V controlled substances.

(3) All inventory records of controlled substances, including the initial and biennial inventories.

(4) Records of controlled substances distributed or dispensed (i.e., hardcopy prescriptions).

(5) Report of Theft or Loss of Controlled Substances (DEA Form-106).

(6) Registrant Record of Controlled Substances Destroyed (DEA Form-41).

(7) Records of transfers of controlled substances between pharmacies.

(8) Current facility DEA registration certificate.

j. Routine inventories. The pharmacist should maintain a perpetual inventory system for all scheduled medications stored in the pharmacy. The pharmacist (or designee) and a physician (or designee) should

jointly conduct a physical inventory of all controlled substances assigned to the pharmacy on a monthly basis, preferably on the last day of each month. The Pharmacist (or designee) and Clinical Director (CD) (or designee) should jointly sign the monthly inventory.

(1) Further validation of controlled substances should be conducted using a printout of monthly purchases of controlled substances from the VA Prime Vendor system's medication wholesaler. This externally generated document must be compared by the pharmacist and physician (or designee) with on-site records to validate medications ordered and on-hand, as compared to the monthly inventory. The monthly inventory is sent through the respective Regional Pharmacy Consultant to the IHSC Chief Pharmacist by the 10th of each month for review;

(2) A copy of the Monthly Narcotics and Other Controlled Substances Form (IHS-174) and the monthly printout from the VA Prime Vendor of all controlled substances should be maintained with the controlled substance records. The Regional Pharmacy Consultant should audit controlled substances records during his or her periodic site visits; and

(3) All records concerning controlled substances must be maintained for at least 10 years for inspection and copying by duly authorized DEA officials. Records and inventories of Schedule II controlled substances must be maintained separately from all other records of the pharmacy. All records and inventories of Schedule III, IV and V controlled substances must be maintained either separately from all other records or in such a manner that the information required is readily retrievable from the ordinary business records.

k. Transfer of custody of controlled substances between pharmacists or other parties. A change of medication custody involving IHSC personnel having custody of scheduled medications requires a written transfer of custody.

(1) This written transfer of custody should include the name of departing and arriving custodians; date and time of inventory; listing of the medication's name, strength and dosage form; and the amount of medication at the time of transfer.

(2) Joint transfer of custody. Whenever possible, a joint written and signed inventory by the departing and arriving custodians should be taken.

(3) No joint transfer possible. If a joint inventory between the departing and arriving custodians is not possible, a physician or qualified

designee should temporarily accept custody by means of a joint written inventory with the departing custodian until the arrival of the replacing custodian.

(4) Transfer of custody of controlled substances from intake. Incoming controlled substances without an appropriate transfer of custody form should be handled immediately by initiating and signing a custody form. This process should be performed by two medical staff personnel.

(5) Transfer of controlled substances upon detainee departure. Outgoing controlled substances should be documented using a transfer of custody form. This should be performed by two medical staff personnel.

l. Controlled substances. All controlled substances should be purchased in unit dose, if available, from the VA Pharmaceutical Prime Vendor.

4-6. Prescription preparation. Prescriptions and medications should be ordered, dispensed and administered in a timely manner as prescribed by a health care professional. Prescriptions should be filled by a pharmacist, physician or pharmacy technician who is working under the direct supervision of a pharmacist or physician.

a. Availability of prescriptions. Systems should be in place to assure needed medications are available 24 hours a day, seven days a week. Based on the patient immediacy of need, this system includes:

(1) A facility pharmacist filling a prescription;

(2) Acquiring the medication from the after hour cabinet available when a pharmacist is not present;

(3) Using the patient's supply until the facility can obtain the medication;

(4) Obtaining the medication from a mail order pharmacy (external or internal); and

(5) Obtaining the medication from a local retail pharmacy.

b. Renewals of expired medication orders. Renewals should be reviewed by the provider prior to renewing an expired prescription.

c. Automatic refills. Automatic refills for 'keep on person (KOP)' medication orders that are still valid are not automatically refilled. KOP

prescription refills should be requested via the sick call process and the pharmacist should determine the detainee's need before refilling.

d. Preparation of a prescription by a pharmacy technician. If a pharmacy technician prepares a prescription, the pharmacist (or a physician) should review the prescription and medication prior to dispensing. The prescription labels should contain the initials of both the pharmacy technician and pharmacist.

4-7. Compliance, monitoring and control.

a. External

(1) Compliance with DEA regulations. IHSC pharmacies are licensed only through a DEA site licensure. Purchases, inventory control and record keeping of all DEA controlled substances stored in the pharmacy must comply with DEA regulations. Compliance is the responsibility of the on-site pharmacist;

(2) The pharmacy must comply with applicable federal statutes and regulations including, but not limited to, those listed in Section 3, AUTHORITY, of this document;

(3) DEA Registration Number. The pharmacist must secure and maintain a current facility DEA Registration Number. In the absence of a pharmacist, a physician (or designee) must secure and maintain a current facility DEA Registration Number. Pharmacy registrations are renewed every three years, and the certificate must be maintained at the registered location and kept available for official inspection;

(4) Drug recall system. The pharmacist at each IHSC site should establish and maintain a drug recall system that complies with all FDA requirements; and

(5) MedWatch. The pharmacist should complete and forward a MedWatch Report (Form FDA 3500) to the FDA after each reportable adverse event or product problem. A copy must be retained for local pharmacy files.

b. Internal monitoring and control. Internal processes for medication administration and pharmaceutical monitoring include annual formulary reviews, pharmacy inspections, monitoring for medication errors and other quality improvement activities.

(1) Annual formulary reviews. The IHSC Pharmacy and Therapeutics Committee must conduct an annual formulary review to designate medications approved for dispensing or administration. Criteria for this review include, but are not limited to, patient medicinal need, cost, efficacy, emerging safety issues, and review of look-alike/sound-alike medication names;

(2) Pharmacy inspections. The pharmacist or trained designee should:

Physically inspect all drug storage areas on a monthly basis to ensure the absence of expired, recalled, or deteriorated drugs;

Physically examine the medications in the urgent care cart on a monthly basis and each time that the security seal on the cart is broken. Each IHSC employee who breaks the security seal on the urgent care cart must immediately notify pharmacy that the seal is compromised;

Monitor the proper condition of storage of drugs;

Ensure compliance with the United States Pharmacopeia (USP) Compendia and/or manufacturer recommendations. The pharmacist should report all identified problems to the HSA and IHSC Regional Pharmacy Consultant. The HSA, facility lead pharmacist, and/or IHSC Regional Pharmacy Consultant should formulate and initiate corrective action plans, as appropriate;

Complete the inspection checklist. A locally developed, clinic specific, standardized inspection checklist is used to document internal pharmacy inspections. The completed copies should be maintained in the pharmacy for a minimum of three (3) years;

Conduct the biennial inventory of controlled substances. The pharmacist must conduct a biennial inventory of all DEA controlled substances at least every two years in accordance with DEA regulations;

Report all medication errors. Medication errors should be reported on the Incident Reporting Document under categories that include, but are not limited to, the wrong detainee, wrong drug, wrong dose, wrong administration time and/or omission of medication. The individual responsible for the error, or whoever discovers the error, should verbally notify the prescriber of the medication error and complete an incident report. If the medication was administered to the detainee and an error was noted, the CD or assigned clinician will be notified to determine

if follow up is needed. The CD or assigned clinician will document their decision or patient status in the medical record. The completed incident report should be forwarded to the HSA;

When there is no on site pharmacist, a consultant pharmacist is used for documented inspections and consultation on a regular basis, not less that quarterly;

Conduct the pharmacist review. Before filling a prescription, the pharmacist should review each prescription for known patient allergies, potential drug-drug/drug-disease/drug-medical condition interactions, contraindications and/or duplicate medication therapy. The pharmacist should advise providers as appropriate of any upcoming prescription expirations; and

Conduct risk assessments. The pharmacist should conduct risk assessment activities based on IHSC national guidance and locally identified problem areas. This may include, but is not limited to, literature reviews, drug utilization reviews and local performance improvement (PI) studies.

(3) Pharmacy reports. The pharmacist should submit:

A report of monthly workload statistics for the previous month by the 10th day of each month. This report should include monthly drug expenditures, number of prescriptions filled, number of after hour cabinet medications issued and number of multiple dose pre-packs prepared;

A quarterly narrative report of activities for the previous quarter, by the 10th day of each of the following months: October, January, April and July. The report should include accomplishments, problems and measures taken for resolution, pharmacy staffing updates, completed continuing education courses, meetings attended and facilities visited; and

All reports to the local HSA, the respective Regional Pharmacy Consultant and the IHSC Chief Pharmacist.

c. Pharmacy relocation. Any time a pharmacy moves to a new physical location or the postal address changes at the same location, a new DEA certificate reflecting the different address or location must be obtained. The facility lead pharmacist must notify the DEA about a change in address before the effective date of the move. Pharmacy relocation is not conducted without prior approval from the Regional HSA, IHSC Chief Pharmacist and DEA field office.

4-8. Drug Formulary. Each medical clinic uses the approved IHSC National Drug Formulary. Medical providers must use formulary medications unless there are significant clinical reasons stated in the detainee's eHR to initiate or maintain non-formulary medication therapy. If a detainee arrives on a non-formulary medication and there is a formulary substitute, the detainee must be switched to the formulary product unless there is a documented failure of therapy with the formulary medication, documented allergy to the formulary product, known contradiction to the formulary product, or other clinically significant justification noted in the detainee's eHR that would justify the non-formulary medication. Once a change is made to a formulary substitute, the detainee should be informed.

a. Orientation to the IHSC formulary system. All providers should receive an orientation to the IHSC formulary system and be provided with access to a copy of the formulary.

b. Generic substitutions. Prescriptions filled at contract pharmacies should be filled with "A" rated Orange Book equivalents, if available, unless there is a valid medical reason for utilizing the brand name product; this reason should be documented in the detainee's eHR.

c. Brand name products. Brand name products may be utilized at IHSC staffed pharmacies if they are available at a cost equivalent to generic medications.

4-9. Non-formulary medications. The requesting provider should complete the Request for Non-Formulary Medication form (Form IHSC 067) and the Associate Medical Director (or designee) must approve the request before medication therapy is initiated or continued, unless there is a compelling medical need that would be expected to result in adverse effects, increased morbidity or increased mortality if not initiated before approval.

a. The facility pharmacist should forward all copies of Form IHSC 067 (approved and disapproved) through the respective IHSC Regional Pharmacy Consultant to the IHSC Chief Pharmacist on, at least, a monthly basis.

b. All compounded medications are considered non-formulary items.

c. A new non-formulary request is not required for the continuation of therapy of intra-system transfer patients who previously had a non-formulary medication approved.

d. A new non-formulary request is not required if a detainee previously taking an approved non-formulary medication leaves ICE custody and returns to ICE custody within 90 days.

4-10. Verbal orders. Providers should only use verbal orders for medications when they are off-site or during after-hours or emergency situations, or where a delay of giving the medication is expected to cause significant suffering, injury or death to the detainee. The verbal order may be given to a licensed vocational nurse (LVN), licensed practical nurse (LPN), RN, NP, PA, or pharmacist.

a. Read back. The verbal order should be noted in the detainee's eHR and read back to the provider. The provider should verbally confirm that the order is correct by repeating the order. The person taking the order should note in the detainee's eHR that the order was read back and verified. The provider should co-sign the order within 72 hours or on the provider's next scheduled workday.

b. Verbal orders for Schedule II drugs. The pharmacist should accept verbal orders for DEA Schedule II medications only in bona fide emergency situations in accordance with federal law and DEA regulations. The verbal order must be immediately reduced to writing by the pharmacist. The originating provider should complete the hard copy of the prescription for the order within 24 hours, or by the end of the provider's next scheduled work day, and must deliver the wet-ink signed prescription with the provider's original handwritten prescription to the pharmacy within seven days. Faxed, scanned or electronic versions of Schedule II prescriptions are not acceptable.

c. Verbal orders for drugs other than Schedule II. Verbal orders for medications other than DEA Schedule II items may be given to a LVN, LPN, RN, NP, PA or pharmacist. The originating provider must co-sign the order within 72 hours. For Schedule III through Schedule V medications, the originating provider must deliver a wet-ink signed prescription hard copy for the order to the pharmacy within 72 hours.

4-11. Prescription filling guidelines. Prescriptions are prescribed and filled as follows:

a. Medications discovered during the intake screening. The provider and the pharmacist should review the medications brought to the facility with arriving detainees and determine whether the continuation of the medication is necessary for the detainee's health condition. These medications may be administered to the detainee via pill line on a temporary basis pending IHSC acquisition and issuance of the medication. All incoming medications, except for medications issued by

other facilities for transportation purposes, are the property of the detainee and should be returned to the detainee upon his departure from the facility unless the detainee agrees that destruction of the medication is appropriate. If the detainee requests destruction of the medication, the medication(s) deemed appropriate for destruction should be delivered to the pharmacy for appropriate destruction.

b. KOP. Detainees may be given up to a 30-day supply of KOP medication. KOP medications exclude all controlled substances, in addition to medications requiring distribution through the pill line per IHSC National Formulary.

c. Prescription documentation. The following information is documented for each prescription prior to dispensing:

(1) Prescription number;

(2) Name, signature (electronic signature for those sites with eHR) and title of pharmacist (or designee);

(3) Date and military time of filling; and

(4) Any clarifying information.

d. Patient medication containers (tablet, capsule and liquid).

(1) Medications should be dispensed in plastic containers, except for nitroglycerin, which is dispensed in its original glass container.

(2) Medications purchased in glass containers from a supply source should be transferred to medically appropriate plastic containers prior to dispensing.

e. Prepackaged items for after-hours ambulatory use.

(1) Medications that are prepackaged for after-hours use should bear a label indicating the drug name, strength, quantity, general directions for use, lot number and medication expiration date.

(2) The provider dispensing the medication should fill in the date, detainee name and alien registration number, and prescriber name and title on the prepackaged item before it is delivered to the patient.

f. Medication Labels. Prescription medication labels should include the following information:

(1) Medical clinic name, address, and pharmacy phone number;

(2) Prescription number;

(3) Date of prescription filling;

(4) Detainee name and alien registration number;

(5) Drug name, strength, and quantity;

(6) Directions for use;

(7) Prescriber's name and title;

(8) Pharmacist's name or initials;

(9) DEA cautionary labels, if a scheduled medication; and

(10) Appropriate auxiliary labels, when required.

4-12. Medication Management.

a. Detainee identification. Detainee identification should be verified by at least two methods prior to providing medication or pharmaceutical services to a detainee. Identification measures include requesting the detainee identification wristband, the detainee identification card or detainee date of birth; asking the detainee to state his or her name; or requesting the detainee's complete or partial alien registration number.

b. Detainee medication counseling. Health care providers should ensure that detainees receive counseling for each medication at the initiation of therapy. Health care providers should take measures to ensure detainees understand the counseling that is provided.

(1) Medication counseling may be given on initiation of drug therapy by verbal instruction, written materials or a combination of both. Medication counseling includes:

Name of medication;

Purpose or pharmacological action of the medication;

Directions for use, including frequency of administration;

Significant side effects or interactions; and

Any other relevant information.

c. Consents for medication administration. *See* IHSC Directive 03-16, *Medication Administration* and the associated *IHSC Medication Administration Guide*.

d. Medication administration. *See* IHSC Directive 03-16, *Medication Administration* and the associated *IHSC Medication Administration Guide*.

e. Methods for distribution of medication to detainees. Medications are distributed either through pill line or KOP.

f. Monitoring effects of medications. Health care providers should monitor the effects and efficacy of medications based on the clinical needs of the detainee. This monitoring should include: medical follow up, as indicated; feedback from the detainee; monitoring of side effects; monitoring of laboratory results; evaluation of clinical response to therapy; and monitoring of medication profile and electronic medication administration record (eMAR).

g. Detainee medication profile. A record of all prescription medications administered and dispensed should be maintained in the detainee's eHR and should include: detainee name, alien registration number, drug name, dosage form, strength, instructions for use and the quantity dispensed or administered.

h. Staff training.

(1) The pharmacist, CD or designee should provide in-service education to IHSC staff on appropriate pharmacy, medication or medical supply management topics.

(2) At the direction of the HSA and CD, nursing or other designated staff should receive medication administration training. This training should include: matters of accountability, common side effects and documentation of administration of medications.

i. Transfer medications. Detainees transferred from one detention facility to another must be provided the following quantities of medication:

(1) At least a seven-day supply of medications as ordered by the prescribing authority;

(2) At least a 15-day supply of anti-tuberculosis (TB) medications for detainees being treated for TB; and

(3) At least a 30-day supply of HIV/AIDS medications for detainees being treated for HIV/AIDS.

j. Discharge medications. Medications that are dispensed directly to the detainee upon release from custody require child resistant packaging. Non child resistant packaging may be provided if such consent is provided by the detainee and documented in the eHR. Detainees released from ICE custody must be provided the following quantities of medication:

Up to a 30-day supply of medication as ordered by the prescribing authority.

k. Medication for medical escorts. When requested by the IHSC Special Medical Operations Unit, pharmacies at IHSC operated clinics should provide medications and related supplies for IHSC medical escorts upon receipt of individual written prescriptions from the special medical operations provider.

l. OTC medications from the commissary. If the facility provides a commissary with OTC medications available to the detainees, the facility administrator and facility HSA should jointly review and approve the list of available commissary OTCs, at least on an annual basis.

m. Relevant drug sensitivity and allergy to medication(s) are entered into the patient's eHR.

n. Correctional or health staff who administer of deliver prescription medication to detainees where permitted to do so by state law are trained as needed in matters of security, accountability, common side effects, and documentation of medicines. The training is approved by a clinician designated by the responsible health authority and facility administrator or designee. Documentation of completed training and testing is kept on file for staff who administer or deliver medications

4-13. Possession of medication by detainees. Detainees may only possess medications ordered by or reviewed and approved by IHSC providers.

a. Detainees must not at any time possess:

(1) Controlled substances;

(2) Medications for the treatment of TB; or

(3) Medications for the treatment of psychiatric conditions.

b. A detainee may only possess one container of a particular medication at any given time.

c. Prescription medications are labeled with the detainee's name and alien registration number.

d. Detainees may possess only reasonable quantities of over-the-counter (OTC) medications. A reasonable quantity is defined as a three-day supply.

e. Detainees should possess no more than a 30-day supply or a single unit (e.g., inhaler, eye drops bottle) of any prescription medication. Quantities in excess of these amounts should be turned back into the clinic for appropriate disposition.

f. Detainees do not prepare, dispense, or administer medication except for self-medication programs approved by the facility administrator and responsible physician. Inmates are permitted to carry medications necessary for the emergency management of a condition when ordered by a clinician

4-14. Pharmacy and Therapeutics Committee. The National Pharmacy and Therapeutics (P&T) Committee serves in an advisory capacity to the Enforcement and Removal Operations Assistant Director-IHSC in all areas related to pharmaceuticals. This committee reports to the IHSC Associate Medical Director.

a. Committee Responsibilities. The P&T Committee's primary responsibility is to assure quality and cost effective support of pharmacy related clinical and administrative services and compliance with national standards. This includes, but is not limited to:

(1) Developing and maintaining a national formulary of pharmaceuticals;

(2) Evaluating clinical data, literature and field input for the purpose of formulary modification;

(3) Reviewing and re-evaluating the list of items available on urgent care carts and in first aid kits;

(4) Reviewing reported drug experience and drug defect reports;

(5) Providing recommendations regarding pharmacy directives, appropriate personnel, equipment, and space for effective and efficient pharmacy and medical supply management; and

(6) Reviewing and recommending, in conjunction with other IHSC consultants, extender-prescribing privileges.

b. Committee Membership. The IHSC P&T Committee consists of the following voting members:

(1) Chairperson, IHSC Associate Medical Director;

(2) Committee Director, IHSC Chief Pharmacist; and

(3) Further membership is determined by the Committee Chair and Committee Director with field representation for medical, dental, psychiatric, MLPs, and nursing.

c. Meetings. Members should meet annually and on an as needed basis. The Committee Director should discuss recommendation and follow-up requirements with the Chairperson and prepare and disseminate an agenda at least five days prior to each scheduled meeting.

(1) Minutes. A permanent record (minutes and associated documentation) of proceedings and activities should be kept on file with the Committee Director. Copies of the minutes should be disseminated to members of the Committee and to the HSA and CD at each IHSC staffed site. HSAs should disseminate meeting minutes to all site medical staff.

5. **PROCEDURES:** See the *IHSC Pharmaceutical Service Guide* located within the following folder: ALL GUIDES.

6. **HISTORICAL NOTES:** This policy replaces IHSC Directive 09-02, dated 31 October 2015. . It adds information to: 4-1; 4-1e(3); 4-1e(4), 4-5a, 4-7 (seventh and eighth bullet; 4-12n; and 4-13f. It also adds definitions.

7. **DEFINITIONS**:

Chief Pharmacist – The IHSC Chief Pharmacist serves as the senior pharmacy professional for IHSC. He or she is responsible for the oversight of the pharmacy program throughout the nation at all IHSC staffed facilities. The Chief Pharmacist provides pharmacy consultation, reporting and coordination services. Additionally he or she reviews and revises all national policies and procedures related to pharmacy operations. The Chief Pharmacist is responsible for all pharmacy issues to include, but not limited to, formulary development and maintenance, pharmacist practitioner

scope of practice, competencies for pharmacy staff, and pharmacy supply contracts. The Chief Pharmacist also reviews the RN Guidelines to provide insight on medication regimen options. (IHSC Operational Definition)

Clinical Director (CD) – The Clinical Director is a physician and is the clinical medical authority at a specific facility. Duties include clinically supervising the Staff Physician (if applicable) and mid-level providers, evaluating patient care through an ongoing quality assurance program, providing training and mentoring to health care staff, and evaluating and treating medically complex patients. The CD is board certified in family medicine, internal medicine, or related primary care specialty to maintain employment. (IHSC Operational Definition)

Health Staff – Health staff includes all health care professionals (including contracted staff) as well as administrative and supervisory staff at *IHSC staffed medical clinics.* (IHSC Operational Definition)

Medical Providers – Medical providers include physicians, physician assistants, nurse practitioners, and clinical pharmacists. (IHSC Operational Definition)

Mid-Level Providers – Mid-level providers are nurse practitioners (NPs) and physician assistants (PAs). (IHSC Operational Definition)

Pharmacist – A pharmacist provides pharmaceutical care to patients directly or indirectly, optimizing medication therapy, promoting health, wellness and disease prevention. The pharmacist provides therapeutic consultation regarding evidence-based efficacy, compliance improvement, medication supply, and pharmacoeconomic considerations. Oversight of the pharmacy operation and drug inventory within the pharmacy is his/her responsibility. A pharmacist has received a Bachelor's or Doctorate Degree in Pharmacy and has an active State Board issued pharmacist license.

Pharmacy Staff – Pharmacy staff includes pharmacists and pharmacy technicians.

Pharmacy Technician – A pharmacy technician prepares and dispenses medications and maintains related records for patients in hospital or clinic under supervision of pharmacist. Prepares, packages, labels and distributes medication doses prescribed by physician. Maintains patient medication profile records, utilizing computer. Maintains inventories of drugs and supplies, performing such duties as placing drug and supply orders with vendors, stocking shelves, rotating stock and checking expiration date of pharmaceuticals. Pharmacy technicians have a high school diploma or equivalent as a minimum and have pharmacy technician certification (CPhT) accredited by the National Commission for Certifying Agencies.

8. APPLICABLE STANDARDS

8-1. Performance-Based National Detention Standards (PBNDS)

PBNDS 2011 (As Modified By February 2013 Errata):

1.2, II: Expected Outcomes.

1.2, V., A., 1: General Environmental Health.

1.2, V., B., 9: Poisonous Substances.

1.2, V., D., 1: Needles and Other Sharp Objects.

1.2, V., D., 4: Inventory.

4:3, V., C., 2: Tuberculosis (TB) Management.

4.3, V., C., 4: Bloodborne Pathogens.

4.3, V., G.: Pharmaceutical Management.

4.3, V., H.: Nonprescription Medications.

4.3, V., S.: Delivery of Medications.

4.3, V., U.: Special Needs and Close Medical Supervision.

4.3, V., W.: Continuity of Care.

4.4, V., D.: Preventive Services.

8-2. American Correctional Association (ACA)

Performance-Based Standards for Adult Local Detention facilities, 4th edition;

a. 4-ALDF-4C-38, Management of Pharmaceuticals.

b. 4-ALDF-4C-39, Nonprescription Medication.

Adult Correctional institutions (ACI), 4th edition;

a. 4-4378.

b. 4-4379.

c. 4-4365, Health Appraisal.

d. 4-4366, Health Appraisal.

Performance-based Standards for Correctional Health Care in Adult Correctional institution;

a. 1-HC-1A-35.

b. 1-HC-1A-22.

c. 1-HC-1A-36.

8-3. National Commission on Correctional Health Care (NCCHC):

Standards for Health Services in Jails, 2014:

J-C-05: Medication Administration Training.

J-D-01: Pharmaceutical Operations.

J-D-02: Medication Services.

9. PRIVACY AND RECORD KEEPING. IHSC maintains detainee health records in accordance with the Privacy Act and as provided in the DHS/ICE-013 Alien Health Records System of Records Notice, 80 Federal Register 239 (January 5, 2015). The records in the eHR/eClinicalWorks (eCW) are destroyed ten (10) years from the date the detainee leaves ICE custody. Retention periods for records of minors may differ. Paper records are scanned into the eHR and are destroyed after upload is complete.

Protection of Medical Records and Sensitive Personally Identifiable Information (PII).

9-1. Staff must keep all health records, whether electronic or paper, secure with access limited only to those with a need to know. Staff should lock paper records in a secure cabinet or room when not in use or not otherwise under the control of a person with a need to know.

9-2. Staff should be trained at orientation and annually on the protection of patient medical information and Sensitive PII.

9-3. Staff should reference the Department of Homeland Security *Handbook for Safeguarding Sensitive Personally Identifiable Information* (March 2012) at: (b)(7)(E) when additional information concerning safeguarding Sensitive PII is needed.

10. NO PRIVATE RIGHT STATEMENT. This directive is an internal directive statement of IHSC. It is not intended to, and does not create any rights,

privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.